

Conference of Radiation Control Program Directors, Inc.

Office of Executive Director ◆ 205 Capital Avenue ◆ Frankfort, KY 40601 Phone: 502/227-4543 ◆ Fax: 502/227-7862 ◆ Web Site: www.crcpd.org Central E-mail: staff@crcpd.org

October 16, 2002

Paul H. Lohaus, Director Nuclear Regulatory Commission (NRC) State and Tribal Programs Washington, DC 20555

RE: KI Resolution

Dear Paul:

On behalf of the Conference of Radiation Control Program Directors, Inc. (CRCPD) membership, please find enclosed a resolution relating to the use of potassium iodide (KI) in the event of a large release of radioactive iodine that may require protective action. As noted in the enclosed document, the CRCPD is recommending the following:

- That state and local jurisdictions CONSIDER the use of KI as a prophylactic for the general public in the event of a large release of radioactive iodine that may require protective action, and
- That consideration of state and local jurisdictions be conveyed to the general public, and if the decision is made to distribute or stockpile KI, jurisdictions must develop and implement a public and medical KI educational program, and
- That state and local jurisdictions must consider the criteria on which a
 recommendation for the public to consume KI will be made. Such criteria should
 take into account whether the drug has been pre-distributed or will be provided
 at the time of an event; whether the recommendation is based on a projected or
 actual release of radioiodine and at what exposure level, and the timeliness of any
 such recommendation. The public should be made aware of the process by which
 KI use will be recommended and cautioned against unnecessary or inappropriate
 use of the drug, and
- That state and local jurisdictions consider the potential liabilities of distributing KI to the public and consideration should be given to legislation or other mechanisms that might afford a measure of immunity from lawsuits for those entities and individuals assigned the responsibility for distributing the drug, and
- That the federal government provide funding to support state and local
 jurisdictions in developing and maintaining a continuing program to provide KI to
 the public should the need arise, and
- That state and local jurisdictions may follow the U.S. Food and Drug Administration guidance titled "Potassium Iodine as a Thyroid Blocking Agent in Radiation Emergencies" dated December 2001, and

Board of Directors

Cynthia C Cardwell
Texas

Chairperson-Elect
Richard A Ratliff
Texas

Past Chairperson
Paul J Merges, Ph D.
New York

Treasurer
Terry C. Frazee
Washington

Members-at-Large
Julia A Schmitt
Nebraska

Russell S. Takata Hawaii

Debbie B. Gilley Florida

Office of Executive Director

Executive Director Ronald G Fraass Kentucky

Administrative Officer Patricia C. Gorman Kentucky

SPOR

October 16, 2002 Paul H. Lohaus Page Two

• That the FDA expedite the approval to manufacture KI in smaller dose amounts (65, 32, 16 mg tablets, and in liquid form) for use by children and neonates or withdraw that portion of the December 2001 guidance referencing the minimum effective doses for children.

On behalf of the CRCPD membership, we appreciate your consideration of this information and possible action on the ideas and recommendations that have been provided.

Sincerely,

Ronald G. Fraass

Executive Director

RGF/PCG/ss

Enclosure

CC: Board of Directors/OAS Advisory Representative

Ronald Fraass



CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

RESOLUTION

Relating to: The Use of Potassium Iodide (KI) In the Event of a Large Release of Radioactive Iodine that May Require Protective Action.

WHEREAS: The CRCPD recognizes the complexities, including stockpiling, distribution timing, and distribution logistics surrounding the issue of state and/or local agencies providing KI to the general public, and

WHEREAS: The CRCPD has reviewed current federal guidance on the use of KI, and

WHEREAS: The CRCPD recognizes that the use of KI is not a substitute for evacuation, shelteringin-place, food embargoes or other protective action that would substantially remove a population from the presence of radioactive materials, and

WHEREAS: Exposure to radioiodine could result in acute health effects and an increased risk of future health problems related to the thyroid, and

WHEREAS: The CRCPD recognizes that KI provides protection only against radioiodine and does not provide protection against any other radioactive material that may be present, and

WHEREAS: A very small segment of the general population may be allergic to iodine and at increased risk of sustaining adverse effects if KI is taken as a prophylactic, and

WHEREAS: Studies have shown that the expected benefit (dose savings) to iodine-allergic individuals outweighs the potential for adverse effects.

NOW BE IT RESOLVED:

That state and local jurisdictions CONSIDER the use of KI as a prophylactic for the general public in the event of a large release of radioactive iodine that may require protective action, and

That consideration of state and local jurisdictions be conveyed to the general public, and if the decision is made to distribute or stockpile KI, jurisdictions must develop and implement a public and medical KI educational program, and

That state and local jurisdictions must consider the criteria on which a recommendation for the public to consume KI will be made. Such criteria should take into account whether the drug has been pre-distributed or will be provided at the time of an event; whether the recommendation is based on a projected or actual release of radioiodine and at what exposure level, and the timeliness of any such recommendation. The public should be made aware of the process by which KI use will be recommended and cautioned against unnecessary or inappropriate use of the drug, and

That state and local jurisdictions consider the potential liabilities of distributing KI to the public and consideration should be given to legislation or other mechanisms that might afford a measure of immunity from lawsuits for those entities and individuals assigned the responsibility for distributing the drug, and

That the federal government provide funding to support state and local jurisdictions in developing and maintaining a continuing program to provide KI to the public should the need arise, and

That state and local jurisdictions may follow the U.S. Food and Drug Administration guidance titled [Potassium Iodine as a Thyroid Blocking Agent in Radiation Emergencies] dated December 2001, and

That the FDA expedite the approval to manufacture KI in smaller dose amounts (65, 32, 16 mg tablets, and in liquid form) for use by children and neonates or withdraw that portion of the December 2001 guidance referencing the minimum effective doses for children.

Approved by the CRCPD Membership on May 6, 2002

Paul J. Merges, Ph.D. CRCPD Chairperson